

SUPPORT FOR THE AMENDMENTS

Applicants have amended Claim 1 for clarity and to incorporate the limitations of Claims 10 and 11. Support for amended Claim 1 can be found in Claims 1, 10, and 11, as originally filed. Claims 2-9 and 12-21 have been amended for clarity. Accordingly, support for amended Claims 2-9 and 12-21 can be found in the same claims, as originally filed. Additional support for amended Claim 2 can be found on page 14, lines 14-17, of the specification. Additional support for amended Claim 6 can be found on page 13, line 28, to page 14, line 6, of the specification. Applicants have also added new Claim 22. Support for new Claim 22 can be found in Claim 21, as originally filed.

No new matter has been added. Claims 1-9 and 12-22 are active in this application.

REMARKS/ARGUMENTS

At the outset, Applicants wish to thank Examiner Alstrum Alcevedo for indicating that Claims 10 and 11 are free of the prior art. Applicants respectfully submit that, in view of the present amendments and remarks, all of the pending claims are fully patentable.

Present Claims 1-9 and 12-15 relate to pharmaceutical aerosol formulations to be administered by a pressurized metered dose inhaler, which comprise:

an active ingredient selected from the group consisting of salmeterol, a stereoisomer thereof, and a physiologically acceptable salt thereof, in solution in a propellant system, said propellant system comprising a liquefied HFA propellant, a co-solvent and 0 to 5% w/w water,

wherein said cosolvent is present in an amount which is no more than 35% w/w based on the total weight of said formulation, and

wherein said formulation has a pH of 2.5 to 5.5, and

wherein said pH of said formulation has been adjusted by addition of a mineral acid.

Claims 16 and 17 relate to methods of preparing such a pharmaceutical formulation, and Claims 18-22 relate to methods for the treatment of certain respiratory diseases by administering such a formulation.

The rejection of Claims 1-3, 5-9, 12, 13, and 18-20 under 35 U.S.C. § 102(e) in view of Published U.S. Patent Application No. 2005/0048001 (Cripps et al.); the rejection of Claims 1-3, 5-9, 12, 13, and 18-20 under 35 U.S.C. § 102(b) in view of WO 01/47493 (Cripps WO); and the rejection of Claims 1-4, 13, and 15 under 35 U.S.C. § 103(a) in view of Cripps et al. or alternatively Cripps WO; have been obviated by amendment. As noted above, Claim 1 has been amended to incorporate the limitations of Claims 10 and 11. Applicants submit that amended Claim 1 and the claims dependent thereon are patentable over the cited references for the same reasons that Claims 10 and 11 were not rejected in view of these references. Thus, the rejections are no longer tenable and should be withdrawn.

The rejection of Claims 1-3, 6, 7, 12-14, and 18-21 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 7-10 of U.S. Patent No. 7,347,199 (“the ‘199 patent”); the provisional rejection of Claims 1-3, 5, 15, and 18-20 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1, 3, 6-11, and 13 of co-pending U.S. Patent Application Serial No. 12/225,075 (“the ‘075 application”); and the provisional rejection of Claims 1-3, 5, and 10 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 14, 15, 25, and 26 of co-pending U.S. Patent Application Serial No. 11/408,026 (“the ‘026 application”) have also been obviated by amendment. As for the rejections based on the ‘199 patent and the ‘075 application, Claim 1 has been amended to incorporate the limitations of Claims 10 and 11. Applicants submit that amended Claim 1 and the claims dependent thereon are not made obvious by the referred to claims of the cited references for the same reasons that Claims 10 and 11 were not rejected in view of these references. In regard to the rejections based on the

'026 application, Claim 1 has been amended to incorporate the limitations of Claim 11. Applicants submit that amended Claim 1 and the claims dependent thereon are not made obvious by the referred to claims of the '026 application for the same reasons that Claim 11 was not rejected in view of this reference. For these reasons, the rejections should be withdrawn.

The provisional rejection of Claims 1-3, 5-7, 9-12, and 14-17 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 2, 3, 6, 7, 11, 19, 22, 24, 28-32, 35, 36, 40-47, and 50-52 of co-pending U.S. Patent Application Serial No. 10/504,151 ("the '151 application") in view of U.S. Patent No. 6,716,414 (Lewis et al.) and the provisional rejection of Claims 1-7, 9-12, and 14-17 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1, 3-18, 20-42, 44, and 45 of co-pending U.S. Patent Application Serial No. 10/505,861 ("the '861 application") are respectfully traversed. Specifically, there is nothing in the referred to claims of the cited applications which would make the presently claimed formulations obvious. In particular, there is nothing in the combination of Claims 2, 3, 6, 7, 11, 19, 22, 24, 28-32, 35, 36, 40-47, and 50-52 of the '151 application and Lewis et al. which would suggest a formulation which contains salmeterol, a stereoisomer thereof, or a physiologically acceptable salt thereof, and which has a pH of 2.5 to 5.5. Similarly, there is nothing in Claims 1, 3-18, 20-42, 44, and 45 of the '861 application which would suggest a formulation which contains salmeterol, a stereoisomer thereof, or a physiologically acceptable salt thereof, and which has a pH of 2.5 to 5.5. Accordingly, the rejections should be withdrawn.

The rejection of Claims 1-7 and 10-21 under 35 U.S.C. § 112, first paragraph, for lack of written description and the rejection of Claims 1-7 and 10-21 under 35 U.S.C. 112, first paragraph, for lack of enablement have been obviated by amendment. As the Examiner will

note, Claim 1 has been amended to delete the term solvate. Accordingly, the rejections should be withdrawn.

The rejection of Claims 2-21 under 35 U.S.C. §§ 112, second paragraph, has been obviated by amendment. As the Examiner will note, the claims have been amended such that they are free of the criticisms outlined on pages 7 and 8 of the Office Action.

The objection to Claims 5-8, 10, and 12-17 under 37 C.F.R. § 1.75(c) has also been obviated by amendment. As the Examiner will note, the claims have been amended to remove all multiple dependencies. Thus, the objection should be withdrawn.

The objection to Claim 19 has also been obviated by amendment. Specifically, this claim has been amended such that it is free of the criticism noted on page 2 of the Office Action. Thus, the rejection should be withdrawn.

Applicants submit that the present application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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